

In re: Application of STEINDLER, et al.
Confirmation No: 6329
Application No.: 10/695,600
Examiner: SAJJADI, F. G.
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REMARKS

Claims 30-39 were pending in the application at the time the Office Action was mailed.
Claims 30-39 are rejected. No claims were allowed.

By this amendment, claims 30-32 and 35-37 have been amended and claims 33, 34, 38, and 39 have been canceled. No claims have been added. Therefore, claims 30-32 and 35-37 remain pending in the application.

Claim Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 37-39 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Examiner asserts:

The Rejection set forth on pp. 2-3 of the previous office action dated is maintained for claims 37-39, for reasons of record. Applicants amendment of the claims to recite *ex vivo* culture followed by introduction of the cells into a tissue in an animal subject fails to overcome the rejection, because claim 37 is directed to isolated brain stem cells. As stated in the previous office action, cells may not at once be isolated and be present in the tissue of an animal subject, because they would no longer remain isolated. Thus the rejection of claims 37-39 is maintained for reasons of record and the foregoing discussion.

Claim 37 has herewith been amended to recite the "*ex vivo* culture of claim 30, wherein the multipotent brain stem cells are cultured in medium comprising insulin, putrescine, progesterone, selenite, pituitary extract, transferrin, serum, growth factors, and at least one contact-limiting factor" instead of "brain stem cells are cultured *ex-vivo*...wherein said cultured cells are introduced into a tissue in an animal subject." Claims 38 and 39 have been cancelled.

In view thereof, Applicants respectfully request reconsideration and withdrawal of the instant rejection.

Claims 30-39 were newly rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

According to the Examiner:

Claim 30 is unclear. The claim refers to cells that "appear as phase-bright very dense bodies and exhibit areas of very small..." It is not clear under what conditions said appearance may be observed; i.e. to the naked eye, or under a phase contrast microscope. Claims 31-39 depend from claim 30, and have therefore been included in the rejection.

Claim 30 (from which claims 31, 32, and 35-37 depend) has been amended herewith to recite "[a]n *ex vivo* culture of an isolated population of multipotent, progenitor or precursor brain stem cells that are immunonegative for glial fibrillary protein, nestin and TuJ1 when cultured under conditions that prevent or reduce cell-cell and cell-substrate interactions, wherein the brain stem cells are from a mammal selected from the group consisting of human and mouse." Support for the amendments to claim 30 can be found, for example, on line 25, page 3 through line 1, page 4, lines 5-23, page 6, and Examples 3 and 10.

In view thereof, Applicants respectfully request reconsideration and withdrawal of the instant rejection.

Claim Rejections Under 35 U.S.C. § 112, Written Description

Claims 30-39 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Office Action states:

Applicants argue that claim 30 has been amended to recite "human and murine", and as such the rejection is moot. Applicants arguments have

been fully considered, but not found persuasive. Regarding the amendment of claim 30, the previous office action set forth the reasons why the instant specification only demonstrates possession of a mixed population of human and mouse brain progenitor cells, and further stated that the term murine encompasses the species such as rat and gerbil, for which possession could not be demonstrated. Moreover, the action outline the reasons why Applicants have failed to demonstrate possession of any isolated cell types, given that the mixed culture of brain progenitor cells represent a continuum of cell proliferation and differentiation, that is in part dependent upon culture conditions, and further, an Artisan of skill could not differentiate between Type I and early Type II cells, both of which are immunonegative for specific markers. As such, no sub-population of cells may be demonstrated as isolated.

As amended, claim 30 (from which claims 31, 32, and 35-37 depend) recites "[a]n *ex vivo* culture of an isolated population of multipotent, progenitor or precursor brain stem cells that are immunonegative for glial fibrillary protein, nestin and TuJ1 when cultured under conditions that prevent or reduce cell-cell and cell-substrate interactions, wherein the brain stem cells are from a mammal selected from the group consisting of: human and mouse." Claim 30 therefore no longer recites "human and murine." Claim 31 which depends from claim 30 has been amended to recite "wherein the cells are from a human and the cells are made according to a method comprising the step of culturing a dissociated human brain cell under conditions that inhibit cell-cell and cell-substrate interactions." Claims 33 and 34 which depend from claim 30 have been canceled. Claim 35 has been amended to recite "wherein the multipotent brain stem cells are mouse cells" instead of "wherein the multipotent brain stem cell is a murine cell." Claim 36 has been amended to recite "wherein the multipotent brain stem cells are obtained from a post-mortem mammal selected from the group consisting of: human and mouse" instead of reciting "from a post-mortem animal subject."

Accordingly, withdrawal of these rejections is respectfully requested.

Claim Rejections Under 35 U.S.C. § 112, Enablement

Claims 30-39 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. Claim 30 as amended herein recites "[a]n *ex vivo* culture of an isolated population of multipotent, progenitor or precursor brain stem cells that are immunonegative for glial fibrillary protein, nestin and TuJ1 when cultured under conditions that prevent or reduce cell-cell and cell-substrate interactions, wherein the brain stem cells are from a mammal selected from the group consisting of: human and mouse."

With regard to meeting the enablement requirement of 35 U.S.C. 112, first paragraph, MPEP 2164.08 states that "[a]ll that is necessary is that one skilled in the art be able to practice the claimed invention, given the level of knowledge and skill in the art. Further the scope of enablement must only bear a 'reasonable correlation' to the scope of the claims. See, e.g., *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). See MPEP 2164.01 which cites *United States v. Teletronics, Inc.*, 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988) ("The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with the information known in the art without undue experimentation."). Applicant asserts that because of the high level of skill in the art and the state of the art at the time the application was filed, one of ordinary skill in the art would not have to perform undue experimentation to make and use the invention as claimed.

Applicants submit that the amended claims now overcome the Examiner's rejections. The specification does describe the isolation and culturing of an isolated population of multipotent, progenitor or precursor brain stem cells that are immunonegative for glial fibrillary protein, nestin and TuJ1 when cultured under conditions that prevent or reduce cell-cell and cell-substrate interactions, wherein the brain stem cells are from a mammal selected from the group consisting of: human and mouse as recited in claim 1. See line 25, page 3 through line 1, page 4, lines 5-23, page 6, and Examples 3 and 10. Dependent claims 31, 32, and 35-37 depend on independent

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claim 30 and as such encompass all of the claim limitations of claim 30. These amendments were made solely for purposes of expediting prosecution and are not meant to be construed as surrender of any subject matter. Applicants do not necessarily agree with or acquiesce in these rejections. Applicants reserve the right to further prosecute the subject matter in one or more Divisional or Continuation applications.

In view thereof, Applicants respectfully request reconsideration and withdrawal of the instant rejection.

CONCLUSION

Applicants have made every effort to present claims which overcome the Examiner's assertions, and it is believed that all claims are now in condition for allowance. However, Applicants request that the Examiner call the undersigned (direct line 561-671-3623) if anything further is required by the Examiner prior to issuance of a Notice of Allowance for all claims.

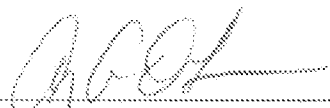
Applicants respectfully request entry of the foregoing amendments and remarks and reconsideration and withdrawal of all rejections. It is respectfully submitted that this application with claims 30-32 and 35-37 is in condition for allowance. Support for the claim amendments can be found on line 25, page 3 through line 1, page 4, lines 5-23, page 6, and Examples 3 and 10. No new matter has been added by virtue of this amendment. If there are any remaining issues or the Examiner believes that a telephone conversation with the Applicants' attorney would be helpful in expediting prosecution of this application, the Examiner is invited to call the undersigned at telephone number shown below.

The Commissioner for Patents and Trademarks is hereby authorized to charge the amount due for any retroactive extensions of time and any deficiency in any fees due with the filing of this paper or credit any overpayment in any fees paid on the filing or during prosecution of this application to Deposit Account No. 50-0951.

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Respectfully submitted,

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